JUL - 5 2007

enpath medical, inc

# 510(K) Summary

**510(k) Number:** K071574

**Date Prepared**

June 7, 2007

**Submitter Information**


| | |
|---|---|
| Submitter's Name/ Address: | Enpath Medical, Inc.<br>2300 Berkshire Lane North<br>Minneapolis, MN 55441 |
| Establishment Registration: | 2183787 |
| Contact Person: | Patrice Stromberg<br>Principal Regulatory Affairs Specialist<br>(763) 951-8181 phone<br>(763) 559-0148 fax<br>pstromberg@enpathmed.com |


**Device Information**

| | |
|---|---|
| Trade Name: | Stiffer Coaxial Micro-Introducer Set |
| Classification Name: | Introducer, Catheter |
| Product Code: | DYB |
| Regulation: | Class II, 21 CFR 870.1340 |
| Panel: | Cardiovascular |

**Performance Standards**

No performance standards applicable tot his product have been developed under Section 514 of the Act.

**Predicate Device**

Enpath Medical, Inc. Coaxial Micro-Introducer Set (K990705)

**Device Description**

The Coaxial Micro-Introducer Kit contains a 21 gauge disposable aspiration and injection needle, a 0.018 inch diameter guidewire, and a coaxial micro-introducer set consisting of a dilator and sheath available in 4F, 4.5F, or 5F.

The modified device contains the same kit configuration as above except that the dilator and sheath are available in 4F or 5F. The inner dilator includes a stainless steel stiffening hypotube. The inner and outer dimensions of the dilator remain the same as the currently marketed Coaxial Micro-Introducer Kit.

**Indications for Use**

The Stiffer Coaxial Micro-Introducer Kit is indicated for use to introduce up to a 0.038 inch guide wire or catheter into the vascular systems following a small 21 gauge needle stick.

**Summary of Non-Clinical Testing**

Performance Testing: The performance testing for this device included testing to verify that the device functions in a safe and effective manner. The performance testing included the device specifications, functional and dimensional testing of the Stiffer Coaxial Introducer and other testing as applicable to the device. Test results verify that the device performs per specification requirements and is equivalent to the predicate device without creating additional risk to the patient or user.

Biocompatibility Testing: The material in the components used to create the Stiffer Coaxial Micro-Introducer Kit has been demonstrated to be biocompatible through biocompatibility testing.

**Summary of Clinical Testing**

No clinical evaluations of this product have been performed.

**Statement of Equivalence**

Through the data and information presented, Enpath Medical, Inc. considers the Stiffer Coaxial Micro-Introducer Kit to be substantially equivalent to the currently marketed Enpath Medical Inc.'s Coaxial Micro-Introducer Kit based on a comparison of the indications for use and the technological characteristics of the kit components. The testing performed confirms that the Stiffer Coaxial Micro-Introducer Kit will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 6 2007

Enpath Medical, Inc.
c/o Ms. Patrice Stromberg
Principal Regulatory Affairs Specialist
2300 Berkshire Lane North
Minneapolis, MN 55441

Re: K071574
Stiffer Coaxial Micro-Introducer Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer Catheter
Regulatory Class: II (two)
Product Code: DYB
Dated: June 7, 2007
Received: June 8, 2007

Dear Ms. Stromberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. S. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number (if known): K071574

Device Name: Stiffer Coaxial Micro-Introducer Kit

Indications for Use:

The Stiffer Coaxial Micro-Introducer Kit is indicated for use to introduce up to a 0.038 inch guide wire or catheter into the vascular systems following a small 21 gauge needle stick.

| Prescription Use ___X___ | | Over-The-Counter Use_____ |
|---|---|---|
| (Part 21 CFR 801 Subpart D) | AND/OR | (21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

---

M. Y. Niellelmeyer
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071574